

2.2 Reconstitution and Administration for Injection of LUPRON DEPOT

- Reconstitute and administer the lyophilized microsphere as a single IM injection as directed below. Visually inspect the drug product for particulate matter and discoloration prior to administration, whenever solution and container permit.
- Inject the LUPRON DEPOT suspension immediately or discard if not used within two hours as the suspension does not contain a preservative.
 1. Visually inspect the LUPRON DEPOT. Do not use the syringe if clumping or caking is evident. A thin layer of powder on the wall of the syringe is considered normal prior to mixing with the diluent. The diluent should appear clear.
 2. To prepare for injection, screw the white plunger into the end stopper until the stopper begins to turn (see Figure A and Figure B).

Figure A:

* administer immediately after reconstituting

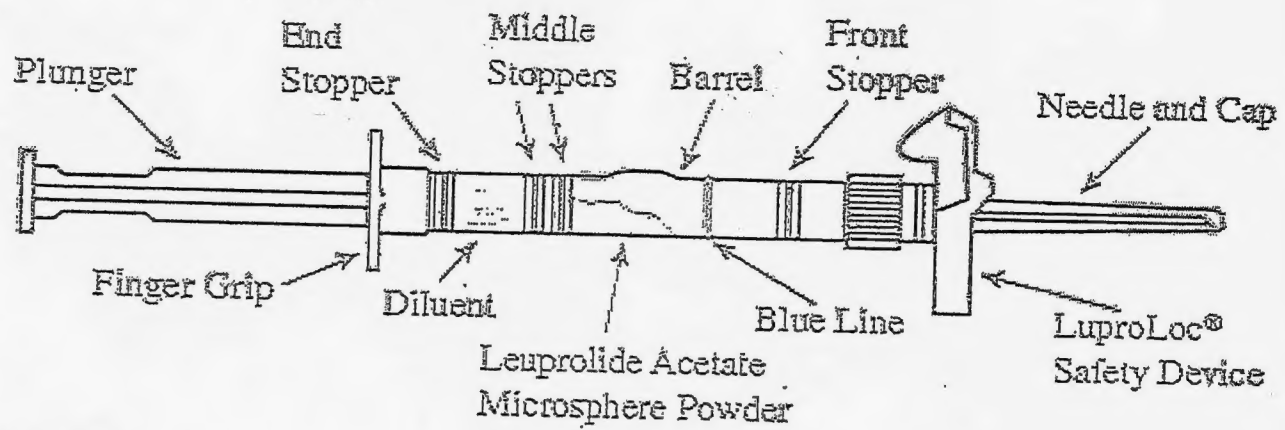
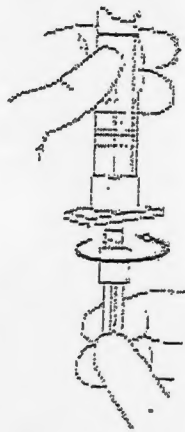
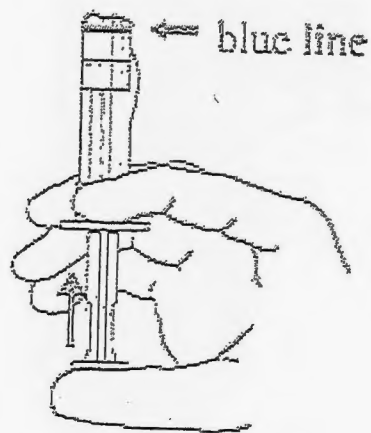


Figure B:



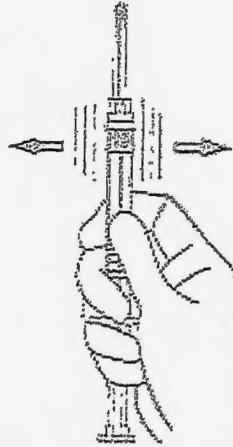
3. Hold the syringe UPRIGHT. Release the diluent by SLOWLY PUSHING the plunger for 6 to 8 seconds until the first middle stopper is at the blue line in the middle of the barrel (see Figure C).

Figure C:



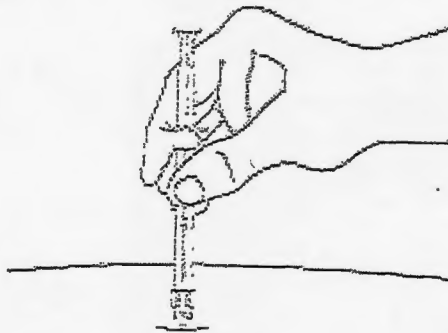
4. Keep the syringe upright. Mix the microsphere powder thoroughly by gently shaking the syringe until the powder forms a uniform suspension. The suspension will appear milky. If the powder adheres to the stopper or caking/clumping is present, tap the syringe with your finger to disperse. Do not use if any of the powder has not gone into suspension (see Figure D).

Figure D:



5. Keep the syringe upright. With the opposite hand pull the needle cap upward without twisting.
6. Keep the syringe upright. Advance the plunger to expel the air from the syringe. The syringe is now ready for injection.
7. After cleaning the injection site with an alcohol swab, administer the IM injection by inserting the needle at a 90-degree angle into the gluteal area, ~~anterior thigh~~, or deltoid. Injection sites should be alternated (see Figure E).

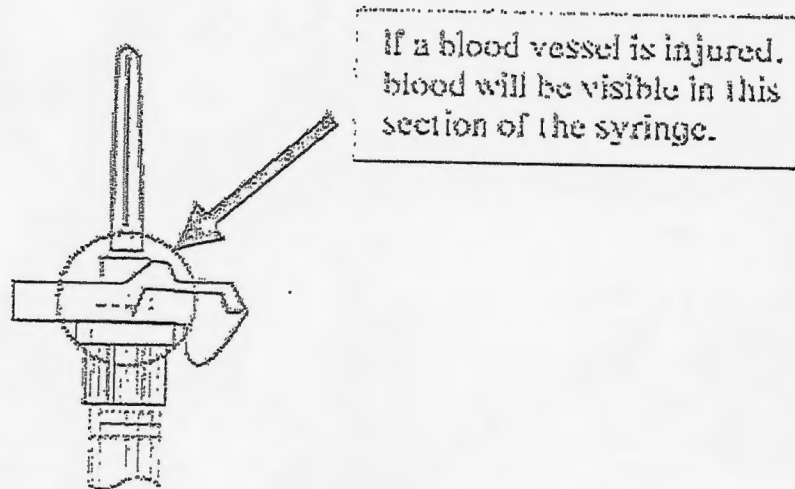
Figure E:



Note: If a blood vessel is accidentally penetrated, aspirated blood will be visible just below the luer lock (see Figure F) and can be seen through the transparent LuproLoc®

safety device. If blood is present, remove the needle immediately. Do not inject the medication.

Figure F:



8. Inject the entire contents of the syringe intramuscularly.
9. Withdraw the needle. Once the syringe has been withdrawn, immediately activate the LuproLoc® safety device by pushing the arrow on the lock upward towards the needle tip with the thumb or finger, as illustrated, until the needle cover of the safety device over the needle is fully extended and a click is heard or felt (see Figure G).

Figure G:



10. Dispose of the syringe according to local regulations/procedures.

INTRAMUSCULAR (IM) INJECTION

PATIENT INSTRUCTIONS

Always wash your hands thoroughly before injecting. This is the best way to prevent infection.

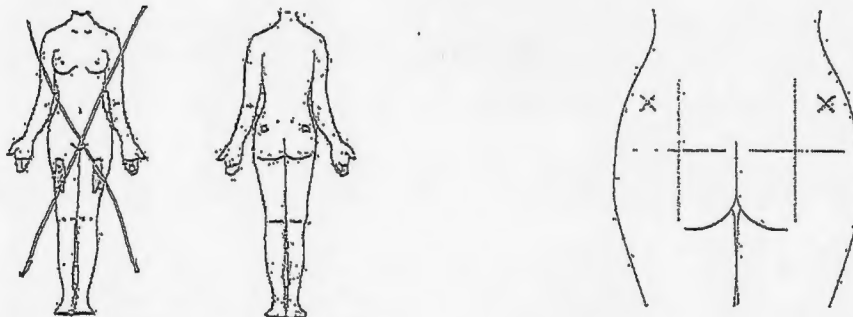
Supplies

- ~~1 cc syringe~~
- ~~22 gauge needle (1 1/2 inch long)~~
- Approved sharps container for syringe disposal
- 2 x 2 inch gauze pad or cotton ball
- Alcohol pads

Preparing the skin

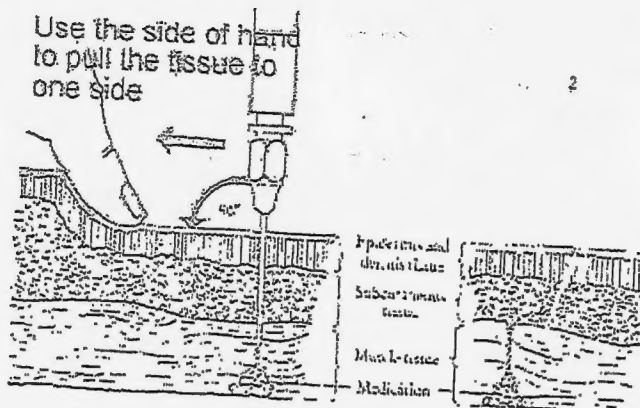
Since the skin is the body's first defense against infection, it must be cleansed thoroughly before a needle is inserted.

Cleanse the skin with an outward circular motion using an alcohol swab, starting at the injection site and moving outward several inches. This motion moves bacteria away from the injection site. Allow the alcohol to dry completely by air.

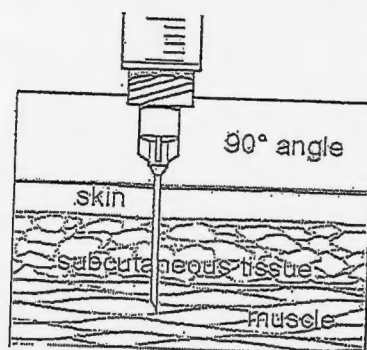


Giving the injection

1. Take the cover off the needle. Be careful not to contaminate the needle. Place the cover on its side.
2. Hold the syringe in one hand like pencil or a dart.
3. Grasp the skin and muscle between the thumb and index finger with your other hand and pinch up. In some people who are thin or who have a lot of muscle, it may not be possible to do this, which is okay.
4. Use a finger to tug the skin area where you will be injecting a bit to one side (this will help prevent medication from leaking out of the injection site)



5. Insert the needle at a 90 degree angle. Quickly and firmly thrust the needle all the way into the skin, however do not "push" the needle into the skin slowly or thrust the needle into the skin with great force. Do not press down on the top of the plunger while piercing the skin.



6. After the needle is completely inserted into the skin, release the skin that you are grasping. Press down on the plunger to release medication into the muscle in a slow, steady pace.

7. As the needle is pulled out of the skin, gently press a 2 x 2 gauze or cotton ball onto the needle insertion site. Pressure over the site while removing the needle prevents skin from pulling back, which may be uncomfortable. The gauze also helps seal the punctured tissue and prevents leakage.

8. It is not serious if you notice blood at the site after the needle is removed. You may have nicked a surface blood vessel when you injected, and blood is following the needle track out to the surface. Simply press the site with a 2 x 2 gauze pad. Also, a small amount of clear fluid may appear at the site. This may be medication that is following the needle track to the surface. Again, apply pressure using a 2 x 2 gauze pad.

Safe needle disposal

- Place the syringe or needle in an approved sharps container.
- Do not recap needles after use as this can cause a needlestick injury. Place the entire needle/syringe unit into the sharps container, uncapped.
- Keep the container out of the reach of children or pets.
- When the container is three quarters full, take it to a health care facility (hospital, pharmacy or doctor's office) for proper disposal.